

AMENDMENTS TO THE CLAIMS

1. (Currently Amended) A paste comprising bacterial cell wall skeleton components [bacteria-CWS] ~~which consists of a bacteria-CWS~~ and an oil wherein the paste has a viscosity of 0.7 poise or less (25 °C).

2. (Currently Amended) The paste comprising bacteria-CWS according to claim 1 wherein the paste has a viscosity between 0.2 and 0.7 poise ~~{at 25 °C}~~.

3. (CANCELLED).

4. (Currently Amended) The paste comprising bacteria-CWS according to ~~any one of claims 1 to 3~~ claim 1 wherein the bacteria-CWS is BCG-CWS.

5. (Currently Amended) The paste comprising bacteria-CWS according to ~~any one of claims 1 to 4~~ claim 1, wherein the oil is squalane.

6. (Currently Amended) The paste ~~comprising bacteria-CWS~~ according to claim 1, wherein the bacteria-CWS is BCG-CWS and wherein the paste comprises 6.6 g to 35.2 g of squalane per about 0.67 g of BCG-CWS.

7. (Original) A process for preparation of a paste comprising bacteria-CWS, which comprises the following steps:

(1) a step of mixing the bacteria-CWS and oils in an organic solvent used as a dispersion-aiding solvent; and

(2) a step of removing the organic solvent in (1) by distillation.

8. (Currently Amended) The process for preparation according to claim ~~17~~⁷ wherein the organic solvent comprises a hydrocarbon solvent and a halogenated hydrocarbon solvent.

9. (Original) The process for preparation according to claim 8, wherein the organic solvent is a hydrocarbon solvent which comprises 5 to 20 % (v/v) of an alcohol solvent.

10. (Currently Amended) The process for preparation according to claim ~~8 or 9~~⁸⁻⁹, wherein the hydrocarbon solvent is heptane or hexane.

11. (Currently Amended) A paste comprising bacteria-CWS ~~obtainable~~
obtained by the process for preparation according to ~~any one of claims 7 to 10~~
claim 7.

12. (CANCELLED)

13. (CANCELLED)

14. (Currently Amended) The paste according to claim 1 that is formulated as an ~~An oil-in-water emulsion which comprises the paste comprising bacteria CWS according to any one of claims 1 to 6 and 11 to 13,~~
and further comprises a surfactant, a stabilizer, and water.

15. (Currently Amended) The oil-in-water emulsion-paste according to claim 14, which comprises 0.66 g to 3.35 g of the bacteria-CWS, and 0.4 wt% to 8 wt% of the oil per 2L of water.

16. (Currently Amended) The ~~oil-in-water emulsion paste~~ according to claim 14 ~~or 15~~, wherein the stabilizer comprises 1 to 10 % mannitol.

17. (Currently Amended) The ~~oil-in-water emulsion paste~~ according to ~~any one of claims 14 to 16~~ claim 14, wherein the surfactant comprises 0.01 % to 3% polyethylenoxysorbitan fatty acid ester.

18. (Currently Amended) The ~~oil-in-water emulsion paste~~ according to claim 17, wherein the polyethylenoxysorbitan fatty acid ester is Tween 80.

19. (Currently Amended) The ~~oil-in-water emulsion paste~~ according to ~~any one of claim 14 to 18~~ claim 14, having the following properties:

(1) the particle diameter of an oil droplet of the emulsion is 0.2 to 30 μm ;

(2) the bacteria-CWS is encapsulated in the oil droplet, and is negative for reaction with lectin.

20. (Currently Amended) A process for ~~preparation of the oil-in-water emulsion preparing the paste~~ according to ~~any one of claims 14 to 19~~ claim 14, which comprises the following steps:

(1) a step of emulsifying a mixture comprising the paste comprising bacteria-CWS according to any one of claims 1 to 10 and 17 to 19, and an aqueous solution containing a surfactant at a temperature higher than the turbidity point; and

(2) a step of adding an aqueous solution containing a stabilizer for dilution.

21. (Currently Amended) The process ~~for preparation~~ according to claim 20 wherein the ~~emulsification~~ emulsifying step in above step (1) comprises the following steps:

(3) a step of emulsifying a mixture comprising the paste comprising bacteria-CWS according to any one of claims 1 to 6 and 11 to 13, and an aqueous solution containing 0.02 % to 0.8 % of a surfactant (rough emulsification step); and

(4) a step of adding an aqueous solution containing a surfactant to the mixture of (3) to adjust the concentration of the surfactant, and vigorously stirring the mixture (complete emulsification).

22. (Currently Amended) A lyophilized formulation ~~obtainable~~ obtained by lyophilizing the emulsion according to ~~any one of claims 14 to 19~~ claim 14.

23. (CANCELLED)

24. (Original) An assembly of bacteria-CWS particles wherein the particle diameter is 0.15 to 6 μm in the particle size distribution.

25. (Currently Amended) The assembly of bacteria-CWS particles according to claim 24, wherein the particle size distribution shows a single peak, as well as D10%: $0.23 \pm 0.05 \mu\text{m}$ and D90%: $0.60 \pm 0.05 \mu\text{m}$.

26. (Currently Amended) A process for preparation of the assembly of bacteria-CWS particles according to claim 24 ~~or 25~~, which comprises dispersing the bacteria-CWS in a solvent containing an aliphatic hydrocarbon solvent.

27. (Original) The process according to claim 26, wherein the solvent is a mixture of an aliphatic hydrocarbon solvent and an alcohol solvent.

28. (Original) The process for preparation according to claim 27, wherein the solvent is a heptane containing 5 to 20 % ethanol.

29. (Currently Amended) A process for identification of a species and/or ~~strains~~ strain of a bacterium from which a bacteria-CWS is derived, which comprises the following steps:

(1) a step of separating and/or extracting the long-chain fatty acid contained in the bacteria-CWS to prepare a long-chain fatty acid fraction, and if necessary, converting the long-chain fatty acid in the long-chain fatty acid fraction into a derivative thereof;

(2) a step of determining the long-chain fatty acid or a derivative thereof in the long-chain fatty acid fraction of (1) by chromatography; and

(3) a step of identifying species and strains of a bacterium from which the bacteria-CWS is derived based on the results of determination (2).

30. (Currently Amended) The process according to claim 29 wherein step (1) comprises a step of labeling the long-chain fatty acid in the long-chain fatty acid fraction to prepare a labeled long-chain fatty acid derivative;.

31. (Currently Amended) A process for assay of the ~~strength~~ immunopotentiating activity of a bacteria-CWS, which comprises the following steps:

(1) a step of separating and/or extracting the long-chain fatty acid contained in the bacteria-CWS to prepare a long-chain fatty acid fraction, and if necessary, converting the long-chain fatty acid in the long-chain fatty acid fraction into a derivative thereof;

(4) a step of determining the content of the long-chain fatty acid or a derivative thereof in the long-chain fatty acid fraction; and

(5) a step of evaluating for an immunopotentiating activity of the bacteria-CWS based on the results of determination (4).

32. (Original) The process according to claim 31, wherein step (1) determining the content of the long-chain fatty acid or a derivative thereof comprises a step of labeling the long-chain fatty acid in the long-chain fatty acid fraction to prepare a labeled long-chain fatty acid derivative.

33. (Currently Amended) The process according to claim 30 ~~or 32~~, wherein a derivative of the long-chain fatty acid is a long-chain fatty acid ester.

34. (Currently Amended) The process according to ~~any one of claims 29 to 33~~ claim 29, wherein the bacteria are those of Mycobacterium or Nocardia.

35. (Original) The process according to claim 34, wherein the bacteria of Mycobacterium are those of BCG.

36. (Currently Amended) The process according to ~~any one of claims 29 to 35~~ claim 29, wherein the long-chain fatty acid is mycolic acid.

37. (Currently Amended) The paste of claim 1 that is formulated as an assembly of bacteria-CWS particles ~~comprising bacteria-CWS according to claims 1 to 6 and 11 to 13 which comprises an assembly of bacteria-CWS particles~~, wherein the particle diameter is from 0.1 μm to 20 μm , ~~preferably from 0.15 to 6 μm , and more preferably 0.2 μm to 2 μm~~ in the particle size distribution.

38. (Currently Amended) ~~The paste comprising bacteria-CWS according to claim 37, wherein the assembly of bacteria-CWS particles exhibit a particle size distribution showing a single peak as well as D10%: $0.23 \pm 0.05 \mu\text{m}$ and D90%: $0.60 \pm 0.05 \mu\text{m}$.~~

39. (Currently Amended) The paste according to claim 37 that is formulated as an An-oil-in-water emulsion which further comprises the paste comprising bacteria-CWS according to claim 37 or 38, a surfactant, a stabilizer, and water.

40. (Currently Amended) The pasteA lyophilized formulation obtainable by lyophilizing the emulsion according to claim 39 that is lyophilized.

41. (Currently Amended) A pharmaceutical composition ~~which consists of the comprising the emulsion according to any one of claims 14 to 19 claim 14 and 39.~~